NAME OF PROJECT. Centralyzed analysis of antiphospholipid antibodies in Europe (in collaboration with APS action)

Subcommittee: Antiphospholipid antibodies/Lupus Anticoagulant

Person responsible (Chair / Principal Investigator): Vittorio Pengo M.D.

Aim / Mandate of the project: Centralized analysis of tests detecting antiphospholipid (aPL) antibodies to confirm laboratory data will be carried in a reference laboratory in Europe (Thrombosis Center, University of Padua, Italy. Director: V Pengo). Both APS patients and aPL carriers are enrolled in this study.

Methodology (in very brief, not more than 1 paragraph): Tubes must be coded (do not use a felt-tip pen, use a cold resistant label) with name of sending centre, patient consecutive number, first 2 letters of patient’s first and last name, and date (gg/mm/aa). For example the first patient from Padua Thrombosis Centre, whose name is Mario Rossi and blood was drawn on Feb 1, 2011 should be labelled as: PADUA 1 MA/RO 01/02/2011. All the labelled tubes must be freezed as quickly as possible after venipuncture to prevent loss of coagulation factors. Freezing the plasma in a freezer at -70°C or below is advisable.

Inclusion / recruitment criteria (if applicable): A data –base to collect demographic, laboratory and clinical data will be sent to each participating centre. Both the type and site of any thromboembolic events at diagnosis must be reported. Pregnancy morbidity is classified according to the latest update on diagnostic criteria for APS. Information about the presence of any associated autoimmune diseases [systemic lupus erythematosus (SLE) or other connective tissue diseases] and the presence of any additional risk factors for thrombosis is also collected.

Year of starting: 2012

Annual report of project: yes

Year of completion (expected): 2015
June 8, 2012

Additional information:

1. What lab will perform the studies.
   *Pengo’s lab in Padova will receive samples from centers in Europe involved in APS diagnosis. This way to go has an educational aim also to alert centers in case of wrong results.*

2. Whether there are other sources of funding for the project, since $5000 is not enough to do the study properly but will probably have in the near future.
   *I fully agree with that. The APS ACTION that is the organization involved in this project has no funding at present. $5000 are needed just for start up in receiving samples from centers (we have to pay for shipping)*

3. How this relates to other quality control efforts such as EQUATH.
   *No relationship. Unfortunately in this field there is no standard material and test are performed as suggested by manufacturers with many bias.*

4. Why the study is limited to European labs.
   *The Pengo’s lab acts as the core lab for Europe. The APS Action involves other core labs and is not limited to EUROPE. The other core labs are trying to get some funding from other organizations for start up of the project.*